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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,854	10/11/2006	Navin N. Thakkar	TKKR-001	5788

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EXAMINER	
HARVEY, JULIANNA NANCY	
ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
06/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/599,854	THAKKAR, NAVIN N.	
	Examiner	Art Unit	
	Julianna N. Harvey	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-22 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-22 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 October 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *26 Oct. 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the invention of Group I (claims 13-22 and 24-27) in the reply filed on 31 March 2009 is acknowledged.

Claims 23, 28, and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 31 March 2009.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(a)-(d) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(a)-(d) as follows:

The U.S. application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the foreign application and in the U.S. application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the foreign application, Application No. 438/MUM/2004, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 438/MUM/2004 fails to provide support for claims 13-22 and 24-27 (the claim limitations of independent claims 13, 17, and 24 are not disclosed in the foreign application).

Information Disclosure Statement

The document cited as PCT/EP98/01018 to Hinze has not been considered because the document has not been properly identified by publication number.

The document cited as 19707420 to Hinze has not been considered because the country code has not been identified.

Drawings

Figures 3A-3E should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 49 (Fig. 17). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "44" has been used to designate both a shaft part and a threaded part. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because Fig. 19 contains a line at the head of the femur that is missing a reference character (the examiner believes the reference character may have been cut off due to the figure not conforming to page margin requirements - see 37 CFR 1.84(g) for acceptable margins). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because of improper grammar (the abstract appears to be a machine translation). Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: it does not contain the proper content (the elements listed below should be included, as appropriate – note that if Applicant amends the specification, Applicant should be careful not to include new matter).

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the

field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

The disclosure is objected to because of the following informalities: it is replete with improper grammar (it appears to be a machine translation). Appropriate correction is required.

The examiner requests that Applicant carefully go through the abstract and disclosure and correct all instances of improper grammar.

Claim Objections

Claims 13-22 and 24-27 are objected to because of the following informalities: the claims are replete with improper grammar (they appear to be a machine translation). Appropriate correction is required.

Claims 14 and 16 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Neither claim 14 nor claim 16 appear to further limit claim 13 as the structural features recited in claims 14 and 16 are already recited in claim 13.

Claim 18 is objected to because of the following informalities: claim 17 states that the proximal fixation device has a "shaft part" whereas claim 18 refers to this feature as both a "shaft" and a "shaft part". The examiner requests that Applicant maintain consistency in the naming of claim elements. Appropriate correction is required.

Claims 20 and 22 are objected to because of the following informalities: each of these claims attempts to further limit an end cap. However, the end cap, though introduced in claim 17, is not positively recited as part of the invention. Appropriate correction is required.

Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

dependent form, or rewrite the claim(s) in independent form. Claim 21 does not appear to further limit claim 17 as the structural features recited in claim 21 are already recited in claim 17.

Claims 24 and 25 are objected to because of the following informalities: claim 24 recites an "intramedullary rod" whereas claim 24 recites both a "rod" and an "intramedullary rod" and claim 25 recites a "rod". The examiner requests that Applicant maintain consistency in the naming of claim elements. Appropriate correction is required.

Claim 25 is objected to because of the following informalities: the claim recites "said end cap" (line 4) though the end cap is not positively recited previously in the claim. Appropriate correction is required.

Claims 25 and 26 are objected to because of the following informalities: claim 24 recites a "fixation device" whereas claims 25 and 26 recite a "proximal fixation device". The examiner requests that Applicant maintain consistency in the naming of claim elements. Appropriate correction is required.

Claim 26 is objected to because of the following informalities: claim 24 states that the intramedullary rod has a "shaft part" whereas claim 26 recites both a "shaft" and a "shaft part". The examiner requests that Applicant maintain consistency in the naming of claim elements. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 14, and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Each of these claims recite that the ductility is at least 15% and the ultimate tensile strength is at least 600 MPa. However, Applicant's disclosure only provides support for a ductility between 15% and 25% and an ultimate tensile strength between 600 MPa and 800 MPa. The examiner also notes that the original disclosure of PCT/IN2005/000103 is consistent with Applicant's present disclosure, not claims 13, 14, and 17. Accordingly, claims 13, 14, and 17, and claims dependent therefrom, contain new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 recites the limitation "said end cap" in line 2. There is insufficient antecedent basis for this limitation in the claim as there is no end cap in claim 24. However, there is an end cap in claim 25. Thus, the examiner is interpreting claim 27 as depending from claim 25, not claim 24.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In claim 24, line 4, Applicant positively recites part of a human ("a fixation device positioned at least partially in said medullary canal"). Thus claims 24-27 include a human within their scope and are non-statutory. A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Vicenzi (US 5,281,225 A). Regarding **claim 13**, Vicenzi discloses an orthopedic implant flexible intramedullary nail comprising: a straight flexible nail (8) of universal length being adapted for insertion into a medullary canal of a bone and capable of

repositioning and fixing fragments of bones, the nail having two ends (9) and a shaft (area located between two ends) where the ends have a blunt conical pathfinder tip (col. 2, lines 41-42) and the shaft and the ends have flexibility such that the nail is capable of being bowed to any angle or any curvature to adapt to the medullary canal and is capable of maintaining the relation of fragments of bone having multiple contact points of fixation (Figs. 1 and 4). Regarding **claim 15**, Vicenzi discloses that the nail is made from 316L stainless steel (col. 2, lines 37-41). Regarding **claim 16**, Vicenzi discloses that the nail has two ends (9) where the ends have a blunt conical pathfinder tip (col. 2, lines 41-42) for better gliding in the medullary canal (Figs. 1 and 4). Vicenzi does not explicitly state that the ductility is at least 15% of elongation of the nail and the ultimate tensile strength is at least 600 MPa (**claims 13 and 14**). However, both ductility and tensile strength are properties of a given material. Because the Vicenzi nail is made from the same material as Applicant's invention (316L stainless steel), the examiner is taking the position that the ductility of the Vicenzi nail is at least 15% of the elongation of the nail and the ultimate tensile strength is at least 600 MPa. Therefore, Vicenzi anticipates **claims 13 and 14**.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Walker (US 4,457,301 A). Walker discloses an article of manufacture used to treat bones fractured into a plurality of fragments, where the bone has a medullary canal, the article of manufacture comprising: a fixation device (13) positionable at least partially in the medullary canal and designed to guide insertion of a flexible nail (11) into the medullary canal covering the plurality of fragments, the fixation device also designed to hold the

flexible nail in the medullary canal while the fragments heal to form bone, wherein the fixation device comprises an intramedullary rod having a shaft part with a plurality of longitudinal grooves (14), each groove being less deep than a diameter of each of the flexible nails and spaced around the periphery of the rod (Figs. 1-5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vicenzi (US 5,281,225 A) in view of Walker (US 4,457,301 A). Regarding **claim 17**, Vicenzi discloses an orthopedic implant intramedullary flexible nail assembly adapted for insertion into a medullary canal of long bones comprising: a plurality of flexible intramedullary nails wherein each of the intramedullary nails comprises a straight flexible nail (8) of universal length being adapted for insertion into the intramedullary canal of long bones and capable of repositioning and fixing fragments of bones, the nail having two ends (9) and a shaft (area located between two ends) where the ends have a blunt conical pathfinder tip (col. 2, lines 41-42) and the shaft and the ends have flexibility such that the nail is capable of being bowed to any angle or any curvature to adapt to the medullary canal and is capable of maintaining the relation of fragments of bone having multiple contact points of fixation; and a proximal fixation

device (2) comprising an intramedullary rod having a shaft part, the intramedullary rod having a head portion adaptable to an end cap and temporarily adaptable to a suitable targeting device (threaded hole 5 can receive handle 7 and could also receive a threaded end cap) (Figs. 1 and 4). Vicenzi does not explicitly state that the ductility is at least 15% of elongation of the nail and the ultimate tensile strength is at least 600 MPa. However, both ductility and tensile strength are properties of a given material. Because the Vicenzi nail is made from the same material as Applicant's invention (316L stainless steel), the examiner is taking the position that the ductility of the Vicenzi nail is at least 15% of the elongation of the nail and the ultimate tensile strength is at least 600 MPa. Therefore, this limitation of **claim 17** is also satisfied by Vicenzi. Regarding **claim 18**, Vicenzi discloses that the shaft (area located between ends 9) of the proximal fixation device (2) has a hole (4) for receiving an interlocking screw (4a), wherein the hole is placed in either a transverse direction or an angled direction to a long axis of the shaft part of the proximal fixation device to receive the interlocking screw (Fig. 1). Vicenzi fails to disclose that the proximal fixation device has a plurality of longitudinal grooves spaced around a periphery of the intramedullary rod (**claim 17**), that the intramedullary rod is tapered to a blunt point at a distal end (**claim 17**), that the shaft of the proximal fixation device has a plurality of holes (**claim 18**), that each of the grooves is less deep than the diameter of one of the flexible nails and the grooves are equally spaced around the periphery of the intramedullary rod for holding the flexible nails apart from one another (**claim 19**), and that the intramedullary rod distal end tapers to a blunt point for easy insertion into the medullary canal (**claim 21**). Walker teaches a proximal fixation

device (13) that has a plurality of longitudinal grooves (14) spaced around a periphery of the fixation device, which is tapered to a blunt point (15) at a distal end (Fig. 2). The grooves of the Walker fixation device are less deep than the diameter of one of the flexible nails (11) and are equally spaced around the periphery of the fixation device (Figs. 2-5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the Vicenzi fixation device with the Walker fixation device (**claims 17, 19, and 21**) as the Walker fixation device is designed to hold the pins in position to support the fracture during healing (col. 2, line 68 through col. 3, line 3 of Walker). It would have then been obvious to provide the Walker fixation device with a longitudinal threaded hole (**claim 17**), as suggested by Vicenzi, in order to provide means to insert the fixation device. It would have been further obvious to provide the Walker fixation device with an angled hole to receive an interlocking screw (**claim 18**), as suggested by Vicenzi, as doing so provides means for fixing the fixation device to the bone. It would have been further obvious to construct the modified Walker fixation device with a plurality of angled holes (**claim 18**), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vicenzi (US 5,281,225 A) in view of Walker (US 4,457,301 A) as applied to claim 17 above, and further in view of Ender (US 4,467,793 A). Vicenzi and Walker disclose the claimed invention except that the intramedullary rod and end cap are made from material comprising one of 316L or 316LVM stainless steel or other biocompatible material.

Ender teaches an orthopedic implant assembly wherein flexible nails (4) are held in place by a proximal fixation device (5) having a threaded (21) opening (6) and the opening is covered by a threaded (20) end cap (18) (Figs. 1 and 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the proximal fixation device with a threaded end cap, as suggested by Ender, as the end cap can be used to cover the longitudinal threaded hole and prevent tissue ingrowth into the hole. It would have been further obvious to make the intramedullary rod and end cap from 316L or 316LVM stainless steel or other biocompatible material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vicenzi (US 5,281,225 A) in view of Walker (US 4,457,301 A) as applied to claim 17 above, and further in view of Haas (US 5,976,140 A) and Grotz (US 5,968,078 A). Vicenzi and Walker teach the claimed invention except that the end cap comprises a head part with a plurality of holes to retain a plurality of hooked cut ends of the flexible nails and a shaft part for attachment with the head portion of the proximal fixation device. Haas teaches an end cap (4) with a shaft part designed to be attached to a head portion of a proximal fixation device (2) (Fig. 1). The head part of the Haas end cap extends past the outer periphery of the Haas proximal fixation device (Fig. 1). Grotz teaches a proximal fixation device (2) wherein a cap (3) has a plurality of holes (9) to retain hooked cut ends of a flexible structure (Fig. 4A). It would have been obvious to further modify

Vicenzi such that the Walker proximal fixation device is covered with an end cap having a head part extending past the outer periphery of the proximal fixation device and a shaft part for attachment with the proximal fixation device, as suggested by Haas, and the head part having a plurality of holes, as suggested by Grotz, as the end cap can cover the longitudinal threaded hole to prevent tissue ingrowth and act as means to secure the ends of the flexible nails.

Claims 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (US 4,457,301 A) in view of Haas (US 5,976,140 A) and Grotz (US 5,968,078 A). Regarding **claim 25**, Walker discloses that the rod has a head portion adaptable to an end cap and temporarily adaptable to a suitable targeting device (bore 22 could receive an end cap and a targeting device) and that the rod tapers to a blunt point (15) at a distal end (Figs. 2 and 5). Regarding **claim 27**, Walker discloses that the intramedullary rod is made from biocompatible material (col. 3, lines 34-38). Walker fails to disclose that the end cap comprises a head part with a plurality of holes to retain hooked cut ends of the flexible nails and a shaft part adaptable for final attachment with the head portion of the proximal fixation device (**claim 25**) and that the end cap is made from a biocompatible material (**claim 27**). Haas teaches an end cap (4) with a shaft part designed to be attached to a head portion of a proximal fixation device (2) (Fig. 1). The head part of the Haas end cap extends past the outer periphery of the Haas proximal fixation device (Fig. 1). Grotz teaches a proximal fixation device (2) wherein a cap (3) has a plurality of holes (9) to retain hooked cut ends of a flexible structure (Fig. 4A). Both the Grotz end cap and proximal fixation device are made from a

biocompatible material (col. 3, lines 35-36). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Walker proximal fixation device such that it is covered with an end cap having a head part extending past the outer periphery of the proximal fixation device and a shaft part for attachment with the proximal fixation device (**claim 25**), as suggested by Haas, and the head part having a plurality of holes (**claim 25**), as suggested by Grotz, as the end cap can cover the bore to prevent tissue ingrowth and act as means to secure the ends of the flexible nails. It would have been further obvious to make the end cap from a biocompatible material (**claim 27**), as suggested by Grotz, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (US 4,457,301 A) in view of de la Caffiniere (US 5,192,281 A). Walker discloses the claimed invention except that the shaft has a plurality of holes for a plurality of interlocking screws wherein the holes are placed in either a transverse direction or an angled direction to a long axis of the shaft part of the fixation device to receive the interlocking screws. de la Caffiniere teaches a fixation device (12) designed to hold a flexible nail (14) wherein the fixation device has a plurality of holes (28, 28') angled to the long axis of the fixation device wherein the plurality of holes are designed to receive interlocking screws (30, 30') such that the screws lock the fixation device to bone (Figs. 5-6; col. 2, lines 37-50). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Walker fixation device with a plurality of

holes designed to receive interlocking screws, as suggested by de la Caffiniere, as doing so provides means to lock the fixation device to bone.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., 8:00 a.m. - 4:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/J. N. H./
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